No. 24-1019

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellee,

v.

KEITH M. ELLISON, in his official capacity as Attorney General of the State of Minnesota,

Defendant-Appellant.

On appeal from the United States District Court
for the District of Minnesota
No. 23-cv-02024 (Schiltz, C.J.)

BRIEF OF APPELLEE

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SUMMARY OF THE CASE AND REQUEST FOR ORAL ARGUMENT

Minnesota enacted a new law that regulates the prices charged by manufacturers of generic and biosimilar medicines in sales that occur entirely outside the State. The law applies if the medicine eventually is resold or distributed to a patient in Minnesota by someone—*anyone*—no matter how far removed from the manufacturer's initial sale. The law does not target the brand-name manufacturers that are responsible for high drug costs. And the law imposes a $500,000 penalty on any generic or biosimilar manufacturer that withdraws from the Minnesota market to avoid the draconian monetary liability. The district court applied binding precedent to hold that the Minnesota law violates the dormant Commerce Clause when it directly regulates prices charged in wholly out-of-state transactions. The district court preliminarily enjoined the law as applied to such transactions by the out-of-state members of the Association for Accessible Medicines ("AAM"), the generic and biosimilar industry association, which is appellee here. This Court should affirm that preliminary injunction.

AAM agrees that oral argument would assist the Court in resolving this appeal and requests 15 minutes per side.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eighth Circuit Rule 26.1A, Appellee Association for Accessible Medicines states that it has no parent corporation and that no publicly held corporation owns 10% or more of its stock.

/s/ William M. Jay
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INTRODUCTION

The State of Minnesota enacted a new price-control law with the ostensible goal of controlling the high costs of prescription medications. But that law misses its target and violates the Constitution in the process. It completely exempts brand-name drugs, which are driving the rising overall cost of medication. Instead, it targets *generic* drugs, which are responsible for *reducing* drug prices. And it directly restricts the prices generic drug manufacturers charge in transactions entirely *outside* Minnesota. That is unconstitutional. "A statute directly controlling wholly out-of-state commerce is invalid" under the Commerce Clause. *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022) (citation and quotation marks omitted). Every court that has considered a state law attempting to impose such a nationwide price control has enjoined it. The district court here correctly did the same.

The new law ("the Act")[1] regulates the price manufacturers may charge for any generic or "off-patent" drug, *anywhere in the country*, Act §§62J.842(1)-(2), so long as "somehow, someday, in some way, someone who is *not* a party to the [initial] transaction … sell[s], dispense[s], or deliver[s] the drug to any consumer in Minnesota." Add. 11 (R.Doc. 42 at 11). A manufacturer that raises prices by an amount Minnesota defines as "excessive" can be penalized up to $10,000 *every* day for *every* sale *and* ordered to refund the supposedly excessive revenue. Act

[1] Laws of Minnesota 2023, ch. 57, art. 2, §§22-27 (Minn. Stat. §§62J.841-.846).

§62J.844(3)(a)(4), (a)(6). "Excessiveness" is determined by a rigid formula that does not take manufacturers' costs into account. And the Act does not care whether the Minnesota patient pays the supposedly "excessive price"; it would impose liability on a manufacturer for a medicine later dispensed *for free* to a Minnesota patient, based on the price charged in the initial out-of-state sale. The Act then imposes a $500,000 penalty on manufacturers that withdraw their products from Minnesota. Act §62J.845. Minnesota insists that prices *nationwide* conform to one State's dictates.

This is a clear violation of the Commerce Clause. That is why the Fourth Circuit invalidated a materially identical Maryland drug-pricing law. *See Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019). If Minnesota's law is allowed to stand, other states will produce a tangle of conflicting state laws—exactly the kind of "competing claims of sovereign authority" the Commerce Clause forecloses. *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 158 (2023) (Alito, J., concurring in part and concurring in the judgment) (citation omitted).

The Attorney General disputes this ultimate conclusion but accepts many of its underlying premises. He agrees that the Commerce Clause prohibits states from directly regulating wholly out-of-state transactions; he agrees that *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), did not displace that longstanding

rule; and he agrees the Act *directly* regulates out-of-state transactions. His sole defense is that the price increases the Act regulates—even prices charged between two out-of-state entities—are not *wholly* outside Minnesota because (a) manufacturers choose to be licensed in Minnesota; and (b) the Act's regulation is triggered only if a medicine is eventually sold or dispensed in Minnesota. Neither argument has merit. This Court held in *Styczinski* that Minnesota could not regulate out-of-state transactions even by its own *residents*; it plainly does not acquire worldwide regulatory power over every business it *licenses*. And triggering the Act only when a medicine is resold in Minnesota by some third party—perhaps months later and many steps removed from the initial sale—does not cure the constitutional violation, because the Act still targets the price charged *outside Minnesota*.

On the remaining preliminary-injunction factors, the Attorney General does not challenge the finding of irreparable harm, and he barely addresses the balance of harms or the public interest. He identifies no abuse of discretion. The equities favor enjoining an unconstitutional law; the Attorney General suggests that the Commerce Clause is an exception, but never explains why. The public interest here favors an injunction because the Act is likely to *reduce* the availability of affordable generic and biosimilar medicines, including by spurring supply shortages. Indeed, both of the examples the Attorney General offers to illustrate rising *generic* prices involved price increases attributable to supply shortages. Threatening generic and biosimilar

manufacturers with enormous monetary liability will only exacerbate this problem and make affordable medicines *less* available to patients.

STATEMENT OF THE ISSUES

1. Whether Minnesota may regulate the prices a manufacturer charges for its medicines in transactions entirely outside Minnesota, simply because the medicine is eventually resold or dispensed to a Minnesota consumer by an unrelated third party in an entirely separate transaction.

Relevant authorities: U.S. Const. Art. I, §8, cl. 3 (Commerce Clause)

Styczinski v. Arnold, 46 F.4th 907 (8th Cir. 2022)

2. Whether the district court abused its discretion by preliminarily enjoining the unconstitutional application of the Act to AAM's members.

Relevant authority: *Carson v. Simon*, 978 F.3d 1051 (8th Cir. 2020) (per curiam)

STATEMENT OF THE CASE

I. Generics and biosimilars reduce the high cost of prescription medication.

The cost of prescription drugs is rising, threatening Americans' access to life-saving medications. The blame for those rising costs lies squarely at the feet of brand-name drug manufacturers. Benefiting from the market exclusivity conferred by patents or regulatory statutes, the sponsors of many brand-name products can raise prices without being constrained by competition. The Attorney General knows that full well: he commissioned a task force to "understand why the costs of

prescription drugs are so high," 2-App.-343 (R.Doc. 26-6 at 3), and its report points directly to brand manufacturers. In particular, the threat to affordability comes from practices that block, delay, or discourage patients from using *generic* medications. *See* 2-App.-347-348, 356, 376-378, 380, 382-387 (R.Doc. 26-6 at 7-8, 16, 36-38, 40, 42-47).

Indeed, generic and biosimilar medications are the primary *antidote* to the ever-climbing prices of brand-name drugs—as the task force report recognizes. *E.g.*, 2-App.-376-377, 380-381 (R.Doc. 26-6 at 36-37, 40-41). Through vigorous competition, prices for generic products are "driv[en] … to be a fraction of that of the corresponding brand name drug." U.S. Dep't of Health & Hum. Servs., *ASPE Issue Brief: Understanding Recent Trends in Generic Drug Prices* 1 (Jan. 27, 2016).[2] And the gap between brand and generic prices has only widened over time. "In 2013, brand-name drugs were nearly six times as expensive as generics, but by 2015 they cost 12 times as much, and by 2017 brand-name drugs cost 18 times as much." Dena Bunis, *AARP Report: Generics 18 Times Cheaper Than Brand-Name Drugs*, AARP (Apr. 8, 2019).[3] Often, generic medicines do not see *any* price increase year-over-year, while brand drugs consistently see annual increases. Of the 810

[2] https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//141996/GenericsDrugpaperr.pdf.

[3] https://www.aarp.org/politics-society/advocacy/info-2019/drug-price-report-generics.html.

pharmaceuticals that saw a price increase in 2022, 791 were brand drugs, while only 19 were generics. *See* Anna Wells & Sara Kim, *Over 800 Prescription Medications Got More Expensive in January 2022*, GoodRx Health (Feb. 22, 2022).[4] Minnesota's own data bears this out: the State's Department of Health issued a report identifying 698 price increases in the first part of 2022 that exceeded the threshold under a separate Minnesota drug-price reporting law. *See* 2-App.-441, 456 (R.Doc. 26-7 at 7, 22). Of those 698 increases (covering "686 unique drugs"), "*only nine* were for generic drugs." 2-App.-456 (R.Doc. 26-7 at 22) (emphasis added).

The savings from generics and biosimilars are substantial. Although accounting for 90% of all prescriptions dispensed in the United States, these medicines make up only 17.5% of the total money spent on prescriptions. Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 7-8, 10 (Sept. 2023).[5] Over the last decade, generic and biosimilar medicines have produced nearly $2.9 *trillion* in savings for the healthcare system, with $408 billion in 2022. *Id*. at 7-8. Minnesota realized $5.7 billion in savings from generics and biosimilars in 2022 alone. *Id*. at 16.

But these benefits were not easily won. Generics and biosimilars face

[4] https://www.goodrx.com/healthcare-access/research/january-2022-drug-increases-recap.

[5] https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

significant "barriers … to both enter and remain in the market," Comm. on Homeland Sec. & Governmental Affairs, U.S. Senate, *Short Supply: The Health and National Security Risks of Drug Shortages* 13 (Mar. 2023),[6] such as "intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns," U.S. Food & Drug Admin., *Drug Shortages: Root Causes and Potential Solutions* 22 (Feb. 21, 2020)[7]; *see also* U.S. Dep't of Health & Hum. Servs., *White Paper: Policy Considerations to Prevent Drug Shortages and Mitigation Supply Chain Vulnerabilities in the United States* 3 (Apr. 2, 2024) (generic manufacturers "face difficult economic conditions that stem from low and/or unpredictable sales volumes, prices, and profit margins for many generic drugs").[8] Consequently, generic manufacturers "realize[] significantly lower profit margins … than a brand company realizes on its brand products." 4-App.-651-652 (R.Doc. 17 ¶19); *see also* U.S. Food & Drug Admin., *Drug Shortages*, *supra*, at 23, 41 (similar).

At the same time, the cost to manufacture generics and biosimilars has risen sharply. "Most generic drug manufacturers rely on other companies to produce" the

[6] https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.

[7] https://www.fda.gov/media/131130/download.

[8] https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.

ingredients "for the drugs they produce," Mariana P. Socal, et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 Health Affairs 407, 407 (Mar. 2023),[9] and the "raw material prices for essential drugs" have continued to rise sharply, by as much as 140% in the post-COVID era, *Active Pharmaceutical Ingredients Market Size*, Precedence Research (Jan. 2023).[10]

These intense market pressures can "incentivize reductions in manufacturing costs to potentially unsustainable levels, drive existing [generic and biosimilar] manufacturers out of the market, and deter potential market entrants"—all generating shortages in the supply of life-saving treatments. *See Policy Considerations*, *supra*, at 3. Such supply shortages in critical medicines have increased substantially in recent years, are "approaching record levels," and are depriving patients of access to lifesaving medicines. Christina Jewett, *Drug Shortages Near an All-Time High, Leading to Rationing*, N.Y. Times, May 17, 2023.[11] "Between 2021 and 2022, drug shortages increased by approximately 30 percent," and have produced "devastating consequences for patients and health care providers." *Short Supply*, *supra*, at 5. Among other issues, supply shortages can

[9] https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01120.

[10] https://www.precedenceresearch.com/active-pharmaceutical-ingredient-market.

[11] https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html.

force the price of the shortage drug higher. Indeed, both the examples of generic-drug price increases the Attorney General includes in his opening brief were attributable, in part, to supply shortages. *See* Opening Br. 9; 1-App.-150 (R.Doc. 26-3 at 13).

II. Generics and biosimilars travel along a lengthy supply chain.

AAM's members—the manufacturers of generics and biosimilars—do not usually sell their medicines directly to patients. Those medicines travel along a lengthy supply chain: Manufacturers formulate raw materials into finished pharmaceuticals and sell them to national wholesale distributors, which then resell those products to retail pharmacies, hospitals, or other healthcare facilities, which in turn provide them to patients. Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp. 4-5 (2021)[12]; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2 (Mar. 2005)[13]; *see also* 4-App.-647-648 (R.Doc. 17 ¶¶4, 6); 4-App.-656 (R.Doc. 19 ¶¶4, 6).

Three companies—Cencora, Cardinal Health, and McKesson—control more

[12] https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

[13] https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

than 90% of the wholesale distribution market,[14] and AAM's members' sales to these companies occur entirely outside Minnesota. Add. 4 (R.Doc. 42 at 4). None of AAM's regular members is based in Minnesota. 1-App.-14 (R.Doc. 1 ¶26). Nor are any of the large wholesalers to which they sell.

Manufacturers, including AAM's members, do not set drug prices on a state-by-state or drug-by-drug basis, but typically sell to wholesale distributors in pre-negotiated bulk contracts covering a range of products for resale nationwide. 4-App.-648 (R.Doc. 17 ¶¶5-7); 4-App.-656 (R.Doc. 19 ¶¶5-7). The ultimate prices charged at the wholesale level are determined by numerous market factors, including prices of raw ingredients and other supplies used to produce the medicines, national market forces, and numerous other market actors, such as wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, and others. 4-App.-651-652 (R.Doc. 17 ¶¶18-20); 4-App.-659-660 (R.Doc. 19 ¶¶18-20).

Manufacturers do not control the prices at which wholesalers or retailers resell their drugs, nor do they direct where those drugs are resold. 4-App.-647-648, 651 (R.Doc. 17 ¶¶4, 18); 4-App.-656, 659 (R.Doc. 19 ¶¶4, 18). And given the lengthy and complex drug-supply chain, manufacturers cannot keep their medicines out of

[14] Adam J. Fein, Ph.D., *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, Drug Channels (Oct. 2, 2019), https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.

Minnesota specifically, or segregate and specially price every unit of medicine that will eventually be dispensed in Minnesota. 4-App.-651 (R.Doc. 17 ¶17); 4-App.-659 (R.Doc. 19 ¶17); *see* 1-App.-20 (R.Doc. 1 ¶44).

III. Minnesota enacts a nationwide price control on generics and biosimilars and threatens manufacturers with massive monetary liability.

Notwithstanding that the Attorney General's task-force report unequivocally blames brand manufacturers for high drug prices, Minnesota chose to adopt a law that does *nothing* to reduce the cost of brand-name drugs. Instead, the Act exclusively regulates prices charged for generics and biosimilars—the medicines most responsible for *reducing* the cost of prescription drugs—and subjects manufacturers of these products to potentially massive monetary liability.

The Act prohibits "manufacturer[s]" from "impos[ing], or caus[ing] to be imposed, an excessive price increase" on a "generic or off-patent drug." Act §62J.842(1).[15] The Act does not impose a similar prohibition on drug wholesalers or other entities further down the supply chain; instead, it applies exclusively to generic and biosimilar manufacturers, *id*. §62J.842(1), and it shields "wholesale distributor[s]" and "pharmac[ies]" from liability for imposing an excessive price increase if the price "is directly attributable to additional costs for the drug imposed

[15] "Generic or off-patent drug" is defined to include "any prescription drug for which any exclusive marketing rights granted under the Federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired." Act §62J.841(3).

on the wholesale distributor or pharmacy by the manufacturer of the drug," *id*. §62J.842(3).

In deciding whether a manufacturer's price increase is "excessive," the Act does not factor in the manufacturer's costs, such as increased prices of raw materials, nor does it account for whether the manufacturer makes any profit. Rather, the Act follows a one-size-fits-all formula: a price increase is "excessive" if (adjusted for inflation) it is greater than $30 for a 30-day supply of the drug or a course of treatment lasting less than 30 days, and it exceeds either (1) a 15% increase in the wholesale acquisition cost ("WAC")[16] over the preceding calendar year, or (2) a 40% increase in the WAC over the preceding three calendar years. Act §62J.842(2).

The Act's prohibition is not limited to prices charged in Minnesota; in fact, the Act is indifferent to what price is ultimately charged in Minnesota. The Act prohibits manufacturers from imposing "excessive price increase[s]" on drugs sold either "directly" to a "consumer in [Minnesota]" or indirectly "through a wholesale distributor, pharmacy, or similar intermediary," as long as the drug is eventually "sold, dispensed, or delivered to any consumer in [Minnesota]." Act §62J.842(1).

[16] The term "wholesale acquisition cost" means, "with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available." 42 U.S.C. §1395w-3a(c)(6)(B); *see* Act §62J.841(6) (incorporating federal definition).

Thus, the price charged by an out-of-state manufacturer to an out-of-state wholesaler may be prohibited and serve as the basis for massive monetary liability, even if the drug is "dispensed[] or delivered" *at no charge* to a "consumer in [Minnesota]." And the Act leaves manufacturers no way to escape: it "prohibit[s]" manufactures from "withdrawing" their products "from sale or distribution within [Minnesota] for the purpose of avoiding" the Act's price control. *Id*. §62J.845(1). A violation carries a mandatory penalty of $500,000. *Id*. §62J.845(3).

The Act empowers various state agencies and contractors to notify a manufacturer "of any price increase" that may violate the law's price regulation. Act §62J.844(1). The manufacturer must then submit a "drug cost statement" to the Attorney General or be ordered by a state court to do so. *Id*. §62J.844(2)(a), (3)(a)(1).

The Attorney General and private parties may sue to enforce the Act. Act §62J.844(3)-(4). Upon a finding of liability, the Act authorizes Minnesota courts to impose significant monetary and other liability on a manufacturer. A court may order the manufacturer to relinquish "any money acquired as a result of a price increase" deemed unlawful, and impose a "civil penalty of up to $10,000 per day for each violation," where "every individual transaction … is … a separate violation." *Id*. §62J.844(3)(a)(3)-(6), (b). A court may also order "that drug prices be restored to levels that comply" with the Act's price controls. *Id*. §62J.844(3)(a)(2).

IV. The district court enjoins the Attorney General from enforcing the Act against AAM's members' out-of-state sales.

AAM brought this lawsuit one week after the Act took effect, alleging that the Act violates the dormant Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and the horizontal separation of powers implicit in the Constitution's design. *See* 1-App.-28-31 (R.Doc. 1 ¶¶60-79); *see* Minn. Stat. §645.02 (making the effective date July 1, 2023). Relevant here, the Complaint alleges that the Act violates the Commerce Clause because it directly regulates wholly out-of-state transactions. 1-App.-28 (R.Doc. 1 ¶¶60-63). AAM moved for a preliminary injunction to prohibit the Attorney General from enforcing the Act against its members based on their sales of generics or biosimilars outside Minnesota. *See* R.Doc. 14 at 1. The district court (Chief Judge Schiltz) granted the preliminary injunction.

A. The court first concluded that "AAM ha[d] established that it is highly likely to succeed on the merits." Add. 20 (R.Doc. 42 at 20).

The court found that, as the Attorney General had "confirmed" at oral argument, the Act "subjects manufacturers to liability as a result of sales that take place wholly outside of Minnesota." Add. 8 (R.Doc. 42 at 8). This, the court held, is unconstitutional—it could find no "support for the notion that the dormant Commerce Clause permits Minnesota to directly regulate a sale that occurs in another state simply because the product eventually makes its way into Minnesota."

Add. 9 (R.Doc. 42 at 9). "To the contrary," the district court recognized that this Court's decision in *Styczinski v. Arnold*—which addressed another Minnesota law regulating "transaction[s] anywhere in the world between a bullion trader and a Minnesota resident," 46 F.4th at 913—had recently and unequivocally "rejected" just "such an expansive notion of an individual state's power to regulate commerce occurring in other states," Add. 9 (R.Doc. 42 at 9). Indeed, the court found the Act to be on "weaker" footing than the law in *Styczinski*, which "regulated only transactions that involved" a Minnesota resident, whereas the Act "applies to out-of-state drug transactions between parties that have no connection whatsoever to Minnesota." Add. 10-11 (R.Doc. 42 at 10-11).

The court rejected the Attorney General's effort to distinguish *Styczinski* on the theory that manufacturers must be "licensed in Minnesota … for their drugs to be distributed [in the state]" and "know that their drugs will eventually be distributed in Minnesota." Add. 11 (R.Doc. 42 at 11). AAM had submitted uncontroverted declarations establishing that members "sell most of their products in bulk via negotiated multi-drug contracts and do not control where the drugs are resold." Add. 11 (R.Doc. 42 at 11); *see* 4-App.-647-648 (R.Doc. 17 ¶¶ 4-5); 4-App.-656 (R.Doc. 19 ¶¶4-5). Thus, the court reasoned, because "*Styczinski* found that out-of-state sales to actual Minnesota residents did not have a sufficient connection to Minnesota to be regulated," a manufacturer's "knowledge that some of the drugs that it sells to a

non-Minnesota distributor may someday find their way into Minnesota" is also insufficient to justify "Minnesota's direct regulation of that out-of-state sale." Add. 11-12 (R.Doc. 42 at 11-12).

The court also found the Act materially indistinguishable from the Maryland law struck down in *Association for Accessible Medicines v. Frosh*. The court acknowledged that the Maryland law may have had a "slightly broader reach" to the extent it could be violated "without an actual sale or distribution of a drug in Maryland." Add. 13-14 (R.Doc. 42 at 13-14). But the court recognized that the "Fourth Circuit went on" to hold that the Maryland law would be unconstitutional "[e]ven if" it (like the Act) required an in-state sale or distribution, because the law regulated "the initial sale of the drug" that "nearly always took place outside Maryland" and therefore "control[led] the price of transactions that occur[red] wholly outside [Maryland]." Add. 14 (R.Doc. 42 at 14).

Although seeing no meaningful daylight between the Act and the laws invalidated in *Styczinski* and *Frosh*, the district court found the Act easily distinguishable from the California law at issue in *National Pork Producers Council v. Ross*. Add. 12-13 (R.Doc. 42 at 12-13). The "crucial difference" between the California law and the Act, the court found, is that "the California law" "d[id] not attempt to impose liability on out-of-state actors for engaging in out-of-state conduct"; it "regulate[d] in-state actors who engage[d] in in-state conduct," whereas

the Act *directly* regulates out-of-state prices. Add. 13 (R.Doc. 42 at 13). Thus, *Ross* "did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it." Add. 7 (R.Doc. 42 at 7).

Finally, the court held that the Act's provision "impos[ing] a $500,000 penalty on manufacturers" that withdraw their products from Minnesota "reinforce[d] the impermissible extraterritorial nature of the Act." Add. 15 (R.Doc. 42 at 15). This provision, the court held, makes "[t]he extraterritorial reach of the Act … unavoidable, as the only sure way for a manufacturer to avoid liability is to either stop selling drugs altogether or to sell *all* of its drugs—including the vast majority that will never reach Minnesota—only at prices that comply with the Act." Add. 15-16 (R.Doc. 42 at 15-16).

B. The court then turned to the remaining preliminary-injunction factors. With respect to irreparable harm, AAM submitted declarations from two of its member companies, which had "intended to raise prices on certain drugs in a manner that would violate the Act," but "[d]ue to the threat of incurring liability …, ha[d] decided not to proceed with the intended price increases." Add. 16-17 (R.Doc. 42 at 16-17). The court held "the financial injuries … the[se] members will suffer as a result of forgoing the intended price increases" to be irreparable because they "are not recoverable from the State" (due to sovereign immunity) "or anyone else." Add.

17 (R.Doc. 42 at 17).

The court then held that the remaining preliminary-injunction factors are "essentially a wash." Add. 19 (R.Doc. 42 at 19). But because AAM had established both likelihood of success on the merits—the "most important of the [preliminary-injunction] factors," Add. 20 (R.Doc. 42 at 20) (citation omitted)—and irreparable harm, the court granted AAM's motion and enjoined the Attorney General from "enforcing, or taking any other action" under sections 22-23 and 25-26 of the Act against AAM's members "based on any member's sale of generic or off-patent drugs outside of Minnesota." 3-App.-642 (R.Doc. 43 at 1).

The Attorney General appealed. 3-App.-645 (R.Doc. 47).

SUMMARY OF ARGUMENT

The Commerce Clause prohibits a State from directly regulating wholly out-of-state commerce. The district court correctly held that the Act does precisely that and enjoined the law. This Court should affirm.

I. "A statute directly controlling wholly out-of-state commerce is invalid" under the dormant Commerce Clause. *Styczinski*, 46 F.4th at 913 (citation and quotation marks omitted). That longstanding rule has been repeatedly applied by federal courts, including this Court, and was recently reaffirmed by the Supreme Court in *Ross*. The Act violates this clear constitutional rule.

A. The Act regulates the prices generic and biosimilar manufacturers charge for their medicines in wholly out-of-state sales. The Act applies to any transaction, anywhere, in which some of the medicine is *eventually* dispensed or resold by some third party to someone in Minnesota—no matter how far removed the out-of-state transaction may be from the eventual use in Minnesota. Under longstanding precedent, including this Court's decision in *Styczinski*, that is unconstitutional.

The Attorney General argues that a sale between, say, a New Jersey manufacturer and an Ohio wholesaler does not really take place *wholly* outside Minnesota because manufacturers choose to be licensed in Minnesota. This Court rejected that argument in *Styczinski*, when it held that even *residency* in Minnesota—a far stronger attachment to the State than licensure—"does not give the State *carte blanche* to regulate all conduct of residents regardless of where it occurs." 46 F.4th at 914. That rule does not change simply because manufacturers "agree" to "operate in a manner prescribed by federal and state law" when they become licensed in Minnesota. Opening Br. 7 (quoting Minn. Stat. §151.252(d)). A state may not condition access to its markets on a party acceding to unconstitutional regulation. *E.g.*, *Frost v. R.R. Comm'n of State of Cal.*, 271 U.S. 583, 593 (1926).

The Commerce Clause violation is not cured because the Act's price control is triggered by a resale or distribution of a drug in Minnesota, because the Act does

not regulate that in-state sale; in fact, it exempts the entities most likely to sell in or directly into Minnesota (pharmacies and wholesale distributors) from regulation. Instead, the Act "measure[s]" the lawfulness of a sale "according to the price the manufacturer … charges *in the initial sale of the drug*," *Frosh*, 887 F.3d at 671, which occurs entirely outside Minnesota, and it imposes liability on the out-of-state manufacturer even if the patient in Minnesota obtains the medicine for a lower price (or even for free).

B. The Attorney General cannot bypass the Commerce Clause by putting the onus on out-of-state manufacturers to alter their business structures to avoid Minnesota's extraterritorial regulation—requiring manufacturers to enter contracts with wholesalers, pharmacies, and other entities in the drug-supply chain to prevent their products from ever being *resold* into Minnesota. AAM submitted uncontroverted declarations that manufacturers *cannot* segregate their products in this way and, in any event, the law does not require them to. The Attorney General does not identify any case holding otherwise.

C. The Act's imposition of a mandatory $500,000 penalty on manufacturers that withdraw any product from Minnesota reinforces the Act's extraterritorial reach. The Act pushes manufacturers to conform all their prices nationwide to the dictates of Minnesota law by punishing them if their products are sold in Minnesota *and* if they try to leave. This not only underscores the Act's

unconstitutional reach, but also contradicts the Attorney General's effort to justify the Act on the theory that manufacturers *voluntarily* agree to become licensed in Minnesota. Remaining in Minnesota no longer reflects a voluntary choice.

II. The district court correctly held the remaining preliminary-injunction factors favor an injunction. The Attorney General does not challenge the district court's finding that the Act irreparably harms AAM's members, and his perfunctory objections on the balance of harms and public interest are without merit. This Court has held that "it is always in the public interest to protect constitutional rights." *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020) (citation omitted). The Attorney General tries to cabin that holding to First Amendment rights, but no case has ever endorsed such a limit and many have done the opposite. There is no logical reason why the public interest is served by allowing government defendants to continue violating the Commerce Clause, but not other constitutional provisions.

The public interest strongly favors an injunction, apart from the Constitution. The Attorney General does not dispute that the Act's imposition of substantial penalties on generic and biosimilar medicines will make it more difficult for those manufacturers to bring their life-saving medications to market, which will exacerbate the already significant supply-shortage problem plaguing the U.S. healthcare market and lead to higher, not lower, prices for prescription medications.

ARGUMENT

The Attorney General's appeal is confined almost exclusively to the district court's conclusion that AAM is likely to succeed on the merits.[17] The district court faithfully applied this Court's precedent to hold that the Act violates the Commerce Clause because it directly regulates wholly out-of-state commerce. The Attorney General does not object to the court's finding that the Act will irreparably harm AAM's members, and his few quibbles on the remaining factors fall far short of establishing that the district court abused its discretion by enjoining an unconstitutional law that inflicts irreparable injury.

I. The Act violates the Commerce Clause's prohibition on state laws that directly regulate wholly out-of-state commerce.

The district court held that "AAM is likely to prevail on its claim that the [Minnesota law] violates the dormant Commerce Clause insofar as it applies to out-of-state sales or drugs." Add. 16 (R.Doc. 42 at 16). That holding follows from this Court's precedent in *Styczinski*, which is in accord with the decisions of the Supreme

[17] The Attorney General says that a "more rigorous standard" applies in the context of a motion to enjoin a democratically enacted state law. Opening Br. 18 (citation omitted). The "likelihood of success" standard *is* that more rigorous standard, *Rodgers v. Bryant*, 942 F.3d 451, 459, 466 (8th Cir. 2019), and the district court applied that standard in its decision, Add. 5-6 (R.Doc. 42 at 5-6). Indeed, it found AAM "*highly* likely to succeed on the merits." Add. 20 (R.Doc. 42 at 20) (emphasis added). Although AAM preserves the argument that the same standard should govern *all* preliminary injunctions, circuit precedent has settled the standard; it does not ask for *more* than a likelihood of success.

Court and numerous other courts.

A. The Commerce Clause prohibits states from directly regulating transactions that occur wholly outside their borders.

The U.S. Constitution provides that "Congress shall have [the] Power … [t]o regulate Commerce … among the several States." U.S. Const. art. I, §8, cl. 3. This affirmative grant of power includes a "negative command, known as the dormant Commerce Clause," which prohibits States from legislating in ways that regulate or discriminate against interstate commerce. *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995).

While state laws that regulate only in-state conduct may have "incidental" effects on interstate commerce without violating the Constitution, a state law that "directly control[s] wholly out-of-state commerce is invalid" under the Commerce Clause. *Styczinski*, 46 F.4th at 913 (citation and quotation marks omitted). This constraint follows from the "inherent limits o[n] the State's power" under the Constitution—"any attempt directly to assert extraterritorial jurisdiction over persons or property would offend sister States and exceed the inherent limits o[n] the State's power" and therefore "must be held invalid." *Edgar v. MITE Corp.*, 457 U.S. 624, 643 (1982) (plurality opinion) (citation and quotation marks omitted).

Under these settled principles, the Act exceeds Minnesota's authority.

1. The Supreme Court and this Court have consistently recognized that States may not directly regulate wholly out-of-state commerce.

The prohibition on state laws that directly regulate out-of-state commerce has deep roots. More than a century ago, the Supreme Court applied the Commerce Clause to invalidate a Minnesota law requiring out-of-state companies to submit to suit involving a "transaction [that] was in no way connected with Minnesota." *Davis v. Farmers Coop. Equity Co.*, 262 U.S. 312, 314-17 (1923); *accord, e.g.*, *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935) (recognizing that one state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [a product] acquired there," even if the product will later be resold in the regulating state).

A plurality in *Edgar* applied this principle to invalidate an Illinois law regulating certain tender offers (*i.e.*, offers to buy shares of a corporation) affecting Illinois corporations. 457 U.S. at 642-43. The law in *Edgar* empowered Illinois to block a tender offer made by an out-of-state buyer to current shareholders—many of them also living out of state—if it did not meet Illinois's standards of fairness. *Id.* at 626-28, 642. A plurality concluded that the law violated the Commerce Clause because "it directly regulate[d] transactions which take place across state lines, even if wholly outside the State of Illinois." *Id.* at 641. MITE Corporation, the plurality observed, had "shareholders scattered around the country," with only "27% of

[them] liv[ing] in Illinois." *Id*. at 642. By blocking the tender offer, the Illinois law prevented the prospective buyer "from making its offer and concluding interstate transactions … with those [stockholders] living in other States and having no connection with Illinois." *Id*. In fact, "the Act could be applied to regulate a tender offer which would not affect a single Illinois shareholder." *Id*. That, the plurality concluded, is unconstitutional: "Because the Illinois Act purports to regulate directly and to interdict interstate commerce, including commerce wholly outside the State, it must be held invalid." *Id*. at 643.

Subsequent majority opinions have since characterized the *Edgar* plurality opinion as "significantly illuminat[ing] the contours of the constitutional prohibition on extraterritorial legislation." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 333 n.9 (1989). Citing the *Edgar* plurality, the Court has repeatedly recognized the principle that a state law is unconstitutional if it "directly regulates or discriminates against interstate commerce," *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578-79 (1986) (citing, *inter alia*, *Edgar*, 457 U.S. at 640-43 (plurality opinion)), including through direct "application … to commerce that takes place wholly outside of the State's borders," *Healy*, 491 U.S. at 336 (quoting *Edgar*, 457 U.S. at 642-43 (plurality opinion)).

In *Styczinski*, this Court faithfully applied this prohibition to invalidate a Minnesota law that sought to regulate the sale of bullion "between a dealer and a

consumer who lives in Minnesota," wherever the transaction might occur. 46 F.4th at 913 (citation omitted). Because the law regulated "transaction[s] anywhere in the world between a bullion trader and a Minnesota resident," out-of-state traders faced liability "without conducting a single transaction in Minnesota" or ever "set[ting] foot" in the State. *Id*. This Court held the law violated the Commerce Clause because it "applie[d] Minnesota law to commerce wholly outside Minnesota." *Id*.[18]

2. Federal courts have consistently invalidated price controls like the Act under the Commerce Clause.

Every court to consider the issue has applied this constitutional rule to invalidate extraterritorial regulations of prescription-drug prices. For instance, Maryland passed a law that, much like the Minnesota law here, prohibited any

[18] *Styczinski* is in good company. Numerous other courts have invalidated state laws that directly regulated out-of-state transactions. *See, e.g.*, *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 612-16 (9th Cir. 2018) (enjoining a California law that purported to "dictate the method by which" medical-waste companies treated medical waste "outside of California," because it "reach[ed] beyond the borders of California [to] control transactions that occur wholly outside of the State"); *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 833-36 (7th Cir. 2017) (invalidating an Indiana law that regulated "commercial transactions taking place wholly outside" Indiana, if the goods were re-sold by a third party into Indiana); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc) (invalidating a California law that required sellers to pay a 5% premium into an artists' fund as applied to all "sales outside the State"); *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 366-76 (6th Cir. 2013) (invalidating a Michigan law that imposed a "unique-to-Michigan mark designation," even though the law "d[id] not discriminate against interstate commerce," because it "allow[ed] Michigan to dictate where the product can be sold" and thus "control[led] conduct beyond the State of Michigan"); *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 662, 667-68 (7th Cir. 2010) (invalidating an Indiana law regulating title loans entered into outside Indiana).

"unconscionable increase in the price of a prescription drug" for certain generic "essential medicine[s]." *Frosh*, 887 F.3d at 666 (citation omitted). The Fourth Circuit held the law unconstitutional because it directly regulated "conduct that occur[red] entirely outside Maryland's borders" and controlled the "prices … in transactions that [did] not take place in Maryland." *Id*. at 670-72. While the law applied only to drugs "made available for sale" in Maryland (by anyone, even downstream from the manufacturer), the law was not "limit[ed] … to sales that actually occur[red] within Maryland." *Id*. at 671 (citation omitted). Thus, the Maryland law sought "to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland." *Id*. at 672. "This," the Fourth Circuit held, Maryland "cannot do." *Id*.

All other courts confronting similar laws have reached the same conclusion. *See Pharm. Rsch. & Mfrs. of Am. v. Dist. of Columbia*, 406 F. Supp. 2d 56, 60, 68-70 (D.D.C. 2005) (invalidating a District of Columbia law that prohibited sales "that result[] in [a] prescription drug being sold in the District for an excessive price" because the law "regulate[d] transactions that occur[red] wholly out of state") (citation omitted), *aff'd sub nom. Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007); *Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Me. Dep't of Hum. Servs.*, No. Civ. 00-157, 2000 WL 34290605, at *2 (D. Me. Oct. 26, 2000) (similar), *rev'd in part on other grounds sub nom. Pharm. Rsch. & Mfrs. of Am. v.*

Concannon, 249 F.3d 66, 72 n.2 (1st Cir. 2001); *accord Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 246, 261-62 (S.D.N.Y. 2018) (holding that a law prohibiting manufacturers from "pass[ing]-through" any portion of a regulatory fee to customers "violate[d] the Commerce Clause's prohibition on extraterritorial state legislation," because the prohibition was not limited to New York transactions), *rev'd in part on other grounds sub nom. Ass'n for Accessible Meds. v. James*, 974 F.3d 216, 219 (2d Cir. 2020).

3. *Ross* reaffirmed the Commerce Clause's prohibition on direct extraterritorial legislation.

The Supreme Court recently clarified the Commerce Clause's limits on state legislative power, but it did not disturb the rule against *direct* regulation by one state of conduct in another. To the contrary, it confirmed that rule.

Ross addressed a California law that prohibited "the *in-state sale* of whole pork meat" from a pig that had been housed under conditions California deemed cruel. 598 U.S. at 365 (emphasis added). The plaintiffs did not argue that the California law *directly* regulated wholly out-of-state conduct, but instead argued that it violated the Commerce Clause because the law's in-state regulation had "the '*practical effect* of controlling commerce outside [California].'" *Id.* at 371 (emphasis added).

The Court rejected the plaintiffs' "'almost *per se*' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce." *Ross*, 598 U.S. at

375; *see id*. at 371-76. But in doing so, the Court did not disturb the distinct prohibition under the Commerce Clause against state laws that *directly* regulate out-of-state commerce. To the contrary, the Court distinguished the California law from the Illinois tender-offer law invalidated in *Edgar*, because the Illinois law "directly regulated out-of-state transactions." *Id*. at 376 n.1. Indeed, the Ninth Circuit decision that the Supreme Court affirmed had expressly held that "[a] state law is not impermissibly extraterritorial unless it directly regulates conduct that is wholly out of state." *Nat'l Pork Producers Council v. Ross*, 6 F.4th 1021, 1029 (9th Cir. 2019). *Ross* thus left undisturbed the longstanding prohibition applied in *Styczinski*, *Frosh*, and the *Edgar* plurality—as every court to address *Ross*'s holding has concluded. *Accord Interlink Prods. Int'l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023) ("[I]n clarifying that such laws with extraterritorial effects are not prohibited under the dormant Commerce Clause, the Supreme Court [in *Ross*] distinguished them from those in which 'a law [] *directly* regulated out-of-state transactions") (citation omitted); *Nat'l Shooting Sports Found. v. Bonta*, No. 23-cv-0945, --- F. Supp. 3d---, 2024 WL 710892, at *7 n.1 (S.D. Cal. Feb. 21, 2024) (similar).

B. The Act is unconstitutional because it directly regulates the wholly out-of-state sales of generics and biosimilars.

The Act is unconstitutional because it directly regulates the prices at which AAM's members sell their generic and biosimilar products in transactions that occur

entirely outside Minnesota.

The Act prohibits generic and biosimilar manufacturers from "impos[ing] … an excessive price increase" on "any generic or off-patent drug." Act §62J.842(1). That prohibition applies wherever those sales occur—so long as the drug is *eventually* "sold, dispensed, or delivered to a[] consumer in [Minnesota]" by *anyone*, no matter how many steps removed from the manufacturer. *Id*.; *see* 3-App.-551-552 (R.Doc. 39 at 3-4). The Attorney General has conceded that the Act regulates out-of-state transactions based on the subsequent activity of third parties in separate transactions in Minnesota. *See* 3-App.-551-553, 556-557 (R.Doc. 39 at 3-5, 8-9); Opening Br. 3.[19] Thus, the price charged for a generic drug by a New Jersey manufacturer to an Ohio distributor will be regulated by the Act, simply because "somehow, someday, in some way, someone who is *not* a party to the [initial] transaction … sell[s], dispense[s], or deliver[s] the drug to any consumer in Minnesota." Add. 11 (R.Doc. 42 at 11).[20]

Notably, the Act is not targeting in-state harm, unlike (for example) the law of product liability. The manufacturer of a defective product may sometimes be

[19] Those concessions and the Act's plain terms dispense with the Attorney General's assertion that "the Act will only ever apply to conduct that occurs in Minnesota by actors who seek out and maintain a presence in the state." Opening Br. 29.

[20] This distinguishes the Act from the various other Minnesota licensing laws the Attorney General references. *See* Opening Br. 4. Those laws regulate the "dispens[ing]" or "distribut[ing]" of drugs "*in Minnesota*." *Id*. (emphasis added).

haled into court where its product causes harm. *See generally Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 592 U.S. 351 (2021). But the Act does not regulate any charge paid by anyone in Minnesota; even if the medicine were dispensed *for free* in Minnesota, the manufacturer would still face liability based on the price charged in the initial out-of-state sale.

The Act's structure confirms that it targets out-of-state transactions. The law applies solely to "manufacturer[s]," and then to make doubly sure only manufacturers are regulated, the Act exempts "wholesale distributor[s] and pharmac[ies]" from liability "if the[ir] price increase[s] [are] directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer." Act §62J.842(3); *see* 3-App.-565-566 (R.Doc. 39 at 17-18) (Attorney General's counsel agreeing the exemption is "belts and suspenders" to ensure distributors and pharmacies are not regulated). The Act does not, however, provide any similar defense for manufacturers who are compelled to raise the prices of their generics or biosimilars due to changing market conditions outside their control. Given how the generic pharmaceutical industry operates, the Act's preferential treatment of wholesalers and pharmacies means an overwhelming number of the Act's applications will involve wholly out-of-state transactions: AAM's regular members are based outside Minnesota, and they sell primarily to wholesale distributors—the three largest of which are based outside Minnesota. *See*

pp. 9-10, *supra*. Wholesalers, in turn, make their own independent decisions to resell those products to retailers, hospitals, and other healthcare facilities—including in Minnesota. *Id*. Thus, manufacturers—which are targeted—sell out-of-state; wholesalers and retailers—which are shielded—are more likely to sell in-state. That disparity "makes clear that the conduct the Act targets is the upstream pricing and sale of prescription drugs." *Frosh*, 887 F.3d at 671.

The Attorney General does not dispute the Act's reach. The Act is therefore invalid for the same reason as the laws in *Styczinski*, *Frosh*, and *Edgar*—it directly regulates transactions that take place wholly outside the borders of the regulating state.

C. Precedent forecloses the Attorney General's efforts to save the Act.

The Attorney General disputes the conclusion that the Act violates the Commerce Clause, but he accepts many of its underlying premises.

First, the Attorney General accepts the key doctrinal principles on which the district court based its ruling. Although the Attorney General originally argued that after *Ross* only *discriminatory* laws violate the Commerce Clause, *see* R.Doc. 25 at 13-14, 16-17, and even now insists that "discriminatory state laws" are the Commerce Clause's "primary concern," Opening Br. 19, he concedes that the Clause invalidates even non-discriminatory laws, *id*. at 21; *see* 3-App.-584 (R.Doc. 39 at 36). As he must: six Justices in *Ross* rejected the view that the Commerce Clause

applies *only* to discriminatory state laws. 598 U.S. at 392 (Sotomayor, J., concurring in part); *id*. at 396 (Roberts, C.J., concurring in part and dissenting in part); *see* Add. 21-23 (R.Doc. 42 at 21-23).[21] More fundamentally, the Attorney General does not dispute that *Ross* preserved the prohibition on state laws that directly regulate wholly out-of-state commerce. He conceded the point at argument below, 3-App.-572-573 (R.Doc. 39 at 24-25), and his opening brief (correctly) reads *Ross* not only to have accepted the plurality decision in *Edgar* as a correct application of the Commerce Clause, but to have confirmed "that the dormant Commerce Clause still prohibits state regulation of commerce taking place 'wholly outside' the state involving individuals 'having no connection with [the regulating state].'" Opening Br. 21-22 (quoting *Ross*, 598 U.S. at 376 n.1); *see* Add. 7 (R.Doc. 42 at 7) (recognizing same).

Second, the Attorney General does not dispute that the Act directly regulates out-of-state transactions. He conceded that point below as well. 3-App.-574 (R.Doc. 39 at 26); Add. 7 (R.Doc. 42 at 7).

So having accepted that the Commerce Clause prohibits direct regulation and that the Act directly regulates out-of-state transactions, the Attorney General's

[21] Nor did *Ross* adopt a "presumption" that non-discriminatory laws do not violate the Commerce Clause, as the Attorney General suggests (at 20, 22). To the contrary, a majority concluded that the plaintiffs *had* adequately alleged that the California law imposed a substantial burden on interstate commerce, even though the plaintiffs expressly disclaimed any theory of discrimination. *See* 598 U.S. at 393 (Barrett, J., concurring in part); *id*. at 394-403 (Roberts, C.J., concurring in part and dissenting in part).

argument on appeal reduces to the position that the out-of-state prices the Act regulates are not charged "'*wholly* outside' Minnesota." Opening Br. 22 (emphasis added); *accord* Add. 7 (R.Doc. 42 at 7). Specifically, he maintains that sales by AAM's members located *outside* Minnesota to wholesale distributors *outside* Minnesota nonetheless have a sufficient connection to Minnesota because (1) AAM's members "voluntarily" subjected themselves to Minnesota regulation by choosing to be "licensed in Minnesota"; and (2) the Act's liability is triggered only if a manufacturer's product is ultimately dispensed in Minnesota by anyone. Opening Br. 30; *see also id*. at 22, 24, 26-28.

Neither of these purported distinctions has any relevance to the Commerce Clause. Both have been repeatedly rejected by courts, including this Court in *Styczinski*, and the Attorney General has not identified a single decision from any court that supports the Act's constitutionality.

1. Manufacturers' licensure in Minnesota does not empower Minnesota to regulate their out-of-state conduct.

The Attorney General asserts that Minnesota may regulate the out-of-state sales of AAM members because those companies "voluntarily" chose to obtain a license to do business in the State. *E.g.*, Opening Br. 26-28, 30. Minnesota made essentially the same argument in *Styczinski*, and this Court rejected it there. It should do the same here.

In *Styczinski*, Minnesota argued that the Commerce Clause allowed it to

regulate out-of-state bullion sales because the statute was limited to transactions involving Minnesota dealers or Minnesota residents. 46 F.4th at 914. "[B]y domiciling in Minnesota," so the argument went, "dealers inure the benefits of Minnesota law and thus subject themselves to Minnesota regulation." *Id*. This Court rejected that theory—merely "domiciling in Minnesota" does not "subject" entities "to Minnesota regulation." *Id*. The Court acknowledged the law applied only to Minnesota residents and that "residents certainly subject themselves to certain obligations by residing in Minnesota," but that "does not give the State *carte blanche* to regulate all conduct of residents regardless of where it occurs." *Id*. The Attorney General is thus wrong to say the bullion law applied even if "[n]one of the regulated entities [had] any presence in or connection to Minnesota." Opening Br. 29. They all did—this Court simply held those connections "insufficient … to pass muster under the dormant Commerce Clause." Add. 10 (R.Doc. 42 at 10).

The en banc Ninth Circuit reached the same conclusion in *Sam Francis Foundation*. A California law required a "seller of fine art to pay the artist a five percent royalty if 'the seller resides in California *or* the sale takes place in California.'" 784 F.3d at 1322 (emphasis added) (citation omitted). The Ninth Circuit "easily conclude[d]" that the law violated the Commerce Clause "as applied to out-of-state sales by California residents" because the law regulated "sales hav[ing] no necessary connection with the state *other than* the residency of the

seller." *Id*. at 1323 (emphasis added).

These holdings apply with even greater force here. The Attorney General relies on the mere "licensure" of out-of-state companies in Minnesota—a far weaker connection than in-state residence, as the district court recognized. Add. 11 (R.Doc. 42 at 11). To be sure, licensed entities "certainly subject themselves to certain obligations," *Styczinski*, 46 F.4th at 914, but mere licensure, no less than "[m]ere … citizenship," Opening Br. 29, "does not give the State *carte blanche* to regulate all conduct of [the licensed entity] regardless of where it occurs." *Styczinski*, 46 F.4th at 914. In fact, the Supreme Court long ago rejected the view that a business registering in a State and consenting to suit in that forum empowers the State to regulate the entity's activity worldwide in derogation of the Commerce Clause. *See Davis*, 262 U.S. at 314-17; *see also Mallory*, 600 U.S. at 157-64 (Alito, J., concurring in part and concurring in the judgment). A Minnesota license is not even product-specific; obtaining a license in order to distribute one product in Minnesota does not give Minnesota jurisdiction over *every* product in the catalog.

Nor can the Attorney General save the Act by claiming that to obtain a Minnesota license manufacturers must "agree to follow Minnesota laws." Opening Br. 26; *see id*. at 5, 7, 28. A licensee agrees generally "to operate in a manner prescribed by federal and state law and according to Minnesota Rules." Minn. Stat. §151.252(d). But as the Attorney General acknowledged below, 3-App.-555

(R.Doc. 39 at 7), that is not consent to abide by *unconstitutional* regulation.[22] A state may not violate the Constitution "under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold." *Frost*, 271 U.S. at 593; *see W. & S. Life Ins. Co. v. State Bd. of Equalization of Cal.*, 451 U.S. 648, 664, 666, 667-68 (1981) (recognizing *Frost* as good law); *accord Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 601-02, 604-09 (2013) ("unconstitutional conditions" doctrine prohibited municipality from conditioning land-use permit on property owner "agree[ing]" to an uncompensated taking). In particular, a state may not condition access to its market on the imposition of regulations that violate the Commerce Clause, such as a tax on out-of-state operations. *W. Union Tel. Co. v. Kansas ex rel. Coleman*, 216 U.S. 1, 33-37 (1910) (plurality opinion); *see W. & S. Life Ins. Co.*, 451 U.S. at 662 & n.14.

In short, the Commerce Clause does not authorize Minnesota to leverage its licensing regime governing the sale and distribution of drugs *into* Minnesota to exert control over manufacturers' prices charged anywhere in the country. Accepting the Attorney General's contrary position would blow a giant hole in the Commerce Clause's important limitations on states' ability to regulate conduct outside their borders. If mere licensure is sufficient to empower a state to engage in nationwide

[22] Nor is it the kind of *irrevocable* consent that would be needed to justify the Act's penalty for leaving the Minnesota market. *See* pp. 47-49, *infra*.

regulation in this context, then it is sufficient in *every* context. And the resulting regime of "competing and interlocking local economic regulation," *Healy*, 491 U.S. at 337, will create the exact dynamic the Commerce Clause was designed to avoid—each State seeking to "arbitrarily exalt [its own] public policy … over that of another," *Styczinski*, 46 F.4th at 914 (citation omitted). A manufacturer licensed in all 50 States could be punished if every transaction, everywhere, did not follow the strictest regulation of any State. This Court has already considered that vision of the Commerce Clause in *Styczinski* and rejected it.

2. AAM's members' out-of-state sales do not become subject to Minnesota regulation based on the independent acts of third parties.

The Attorney General's second defense of the Act is equally flawed. He asserts that AAM's members' out-of-state sales are regulable because liability is not imposed unless some of the product is *eventually* sold or dispensed in Minnesota by someone, no matter at what price. Opening Br. 24, 28, 30. But the fact that a product arrives in Minnesota in an entirely separate transaction, perhaps many months later and between third, fourth, or fifth parties many steps down the supply chain, does not convert the *initial* out-of-state transaction between an out-of-state manufacturer and an out-of-state wholesaler into an *in-state* sale that Minnesota may regulate. Nothing in *Styczinski* suggests the constitutional defect it identified would evaporate if the Minnesota resident who purchased the bullion out-of-state later resold it in

Minnesota. And what *Styczinski* rejected by logical implication, *Frosh* and the *Edgar* plurality rejected explicitly.

Recall that the Maryland law in *Frosh* regulated prices charged for prescription medicines that were "made available for sale in Maryland," 887 F.3d at 666 (citation omitted)—a structure similar to the Act's own liability trigger. *See* p. 12, *supra*. The Fourth Circuit recognized that "[t]his structure makes clear that the conduct the Act targets is the upstream pricing and sale of prescription drugs." 887 F.3d at 671. "[B]y its own terms," the Maryland law was "not fixated on the price the Maryland consumer ultimately pays for the drug"; instead the "lawfulness of a price increase [wa]s measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*." *Id*. at 671. The Maryland law was therefore unconstitutional because it "attempt[ed] to dictate the price that may be charged elsewhere for a good." *Id*. at 672. That is exactly what the Act does, and it is unconstitutional for the same reason. *See also Pharm. Rsch. & Mfrs. of Am.*, 406 F. Supp. 2d at 69-70 (invalidating drug price-control law even though the law's penalties were not triggered until the drug's eventual resale in the District, because "as soon as that drug [wa]s sold in the District, the manufacturer's out-of-state sale bec[a]me[] the [law's] primary target"); *Legato Vapors*, 847 F.3d at 836 (invalidating Indiana law regulating out-of-state sales of e-cigarettes based on their resale into Indiana).

The Attorney General says *Frosh* is inapposite because the Maryland law, unlike the Act, was triggered "regardless of whether any pill from an out-of-state sale *ever actually made it into Maryland*." Opening Br. 30-31 (citing *Frosh*, 887 F.3d at 666) (emphasis added). That makes no difference. That the Act is *triggered* by an in-state sale or distribution does not change the fact that the Act *regulates* the wholly out-of-state sales of manufacturers—and *those* sales likewise "d[o] not result in a single pill being shipped [in]to [Minnesota]." *Frosh*, 887 F.3d at 671. In any event, *Frosh* did not stop there. The court *also* held that the Maryland law violated the Commerce Clause "[*e*]*ven if* [it] … require[d] a nexus to an actual sale in Maryland," as the district court had interpreted the law, because even under that reading, the law "instruct[ed] manufacturers … as to the prices they are permitted to charge in transactions that do not take place in Maryland." *Id*. at 671-72 (emphasis added). *Frosh* thus directly rejected the Attorney General's effort to bypass the Commerce Clause's direct-regulation prohibition.

The plurality opinion in *Edgar* drives the point home. *Edgar* involved a tender offer for an Illinois corporation with 27% of its shareholders "liv[ing] in Illinois." 457 U.S. at 642 (plurality opinion). The plurality found the law unconstitutional because it "prevent[ed]" the out-of-state offering company from "concluding interstate transactions not only with … stockholders living in Illinois, but also with those living in *other* States and having no connection with Illinois." *Id*. (emphasis

added). In other words, the presence of *other* in-state transactions that Illinois could regulate did not give the state license to regulate separate, out-of-state transactions. So too here: that a third party may resell or redistribute a medicine into Minnesota—a transaction Minnesota is free to regulate—does not give the State authority to regulate the prior, upstream sale between an out-of-state manufacturer and an out-of-state distributor.[23]

The Attorney General tries to distinguish the *Edgar* plurality on the ground that the Illinois law "gave Illinois power to determine whether a tender offer in another state could proceed at all, even though no party to the transaction … had any connection to Illinois whatsoever." Opening Br. 23-24. That is not true. The Illinois

[23] The Attorney General suggests that *Edgar* "was less" a Commerce Clause decision than "one testing the territorial limits of state authority under the Constitution's horizontal separation of powers." Opening Br. 21 n.75 (quoting *Ross*, 598 U.S. at 376 n.1). That is a curious position for the Attorney General to take in light of his successful motion to dismiss AAM's separate claim premised on the "horizontal separation of powers" for failure to state a claim. *See* Add. 24 (R.Doc. 42 at 24). It is even more curious given the Attorney General's concession on the same page of his brief that *Ross* understood the *Edgar* plurality to have been based on the Commerce Clause. Moreover, the *Edgar* plurality was clear that its conclusion rested in the Commerce Clause: it began by describing the principles governing Commerce Clause challenges, including the prohibition on "direct regulation" of interstate commerce; it then concluded that the Illinois law was unconstitutional because "[t]he Commerce Clause [] precludes the application of a state statute to commerce that takes place wholly outside of the State's borders" and the Illinois law was "a direct restraint on interstate commerce [with] sweeping extraterritorial effect." 457 U.S. at 642 (plurality opinion). In any event, the Attorney General does not argue that the academic musings referenced in *Ross*'s footnote affect the disposition of this appeal.

law applied only to tender offers where (1) "shareholders located *in Illinois* own[ed] 10% of the class of equity securities subject to the offer"; or (2) "any two of the following three conditions [we]re met: [a] the corporation ha[d] its principal executive office *in Illinois*, [b] [was] organized under the laws *of Illinois*, or [c] ha[d] at least 10% of its stated capital and paid-in surplus represented *within the State*." *Edgar*, 457 U.S. at 626-27 (emphases added). By definition, every application of the Illinois law required "a substantial connection within [Illinois]," Opening Br. 24, and provided protection for a "legitimate state interest," *id*. at 25 (quoting *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 549 (7th Cir. 2003))—but the plurality found the Illinois law unconstitutional anyway. And even if the Illinois law *could* have applied to a transaction with no connection to Illinois, that was not true of the specific *application* of the Illinois law in *Edgar*, which involved a tender offer to shareholders of "a publicly held Illinois corporation," 27% of whom "live[d] in Illinois." 457 U.S. at 642 (plurality opinion).

The Act thus suffers from the very flaw the Attorney General ascribes to the Illinois law in *Edgar*, and it is unconstitutional for the same reason: "the [Minnesota] law gave [Minnesota] power to determine whether to allow a [price increase] by a *Delaware* corporation [for the sale of medicine to] an *Arkansas* [corporation]." Opening Br. 23. That the medicine is later dispensed in Minnesota does not save the Act, because that is not the transaction the Act is regulating.

3. The Attorney General's reliance on *CTS* is entirely misplaced.

In the face of this case law, the Attorney General hangs his hat on *CTS Corporation v. Dynamics Corporation of America*, 481 U.S. 69 (1987). *See* Opening Br. 24-25. That decision did not consider a direct regulation like this one and, of course, it says nothing about this Court's precedent in *Styczinski* decades later. In fact, to the extent it is relevant, *CTS* supports affirmance.

CTS involved an Indiana law that regulated the voting rights that attach to shares issued by an Indiana corporation by "condition[ing] acquisition of control of a[n Indiana] corporation" by a third party "on approval of a majority of the pre-existing disinterested shareholders." 481 U.S. at 72-74. The Indiana law, unlike the Illinois law in *Edgar*, did not regulate Dynamics' tender offer to anyone, or otherwise regulate any out-of-state transaction. *Id*. at 73-74, 91, 93-94. Rather, it regulated matters of "corporate governance," which fall squarely within the State's power to "create corporations, to prescribe their powers, and to define the rights that are acquired by purchasing their shares." *Id*. at 91. For that reason, Dynamics, which had acquired a controlling number of shares of CTS by a successful tender offer, did not argue that the Indiana law violated the Commerce Clause's prohibition on extraterritorial state legislation. Instead, Dynamics asserted an entirely different theory of Commerce Clause liability—that the Indiana law unduly burdened interstate commerce under *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). *CTS*,

481 U.S. at 76-77. And it was in the context of rejecting that *Pike* claim that *CTS* distinguished *Edgar*'s holding that the Illinois tender-offer law was unconstitutional under *Pike*. *Id*. at 89-93.

CTS thus did nothing to undermine the *Edgar* plurality, much less the decades of clear, subsequent precedent invalidating direct regulations. To the contrary: even as *CTS* distinguished the *Edgar* majority, it went out of its way to *reaffirm* the rationale of the *Edgar* plurality, explaining that the Indiana law was not unconstitutional for "subjecting activities" in interstate commerce "to inconsistent regulations" because under laws like Indiana's, corporations "will be subject to the law of only one State." 481 U.S. at 88-89 (citing, *inter alia*, *Edgar*, 457 U.S. at 642). *CTS* thus supports affirmance.

D. The Attorney General cannot avoid the Commerce Clause violation based on supposed restructuring of AAM's members' business operations.

In a last-ditch effort, the Attorney General takes aim at the district court's statement that AAM's members "lack the ability to control where their drugs are distributed" or "lack knowledge that their drugs [might] … wind up in Minnesota." *See* Opening Br. 31-34; Add. 8, 9, 11 (R.Doc. 42 at 8, 9, 11). According to the Attorney General, the Commerce Clause "does not protect firms' chosen 'methods of operation,'" and AAM's members can simply restructure their business operations to prevent the resale of their products by third parties into Minnesota.

Opening Br. 32 (citation omitted). This argument is meritless for multiple reasons.

First, as the Attorney General acknowledges, this argument rests on the assumption that it is *possible* for AAM's members to control where their drugs are re-sold by wholesale distributors, retailers, pharmacies, hospitals, and any other entity in the lengthy drug supply chain. Opening Br. 32 (stating that Commerce Clause challenges "fail when regulated entities *have the ability* to segregate products bound for the regulating state" (emphasis added)). The Attorney General argues that "AAM never claims its members are *actually incapable* of segregating their products for state marketplaces," Opening Br. 32, but that is not true. AAM submitted declarations from two of its member companies explaining that it is *not* possible for them to segregate out and specially price products destined for Minnesota. 4-App.-651 (R.Doc. 17 ¶17); 4-App.-659 (R.Doc. 19 ¶17); *see also* 1-App.-20 (R.Doc. 1 ¶¶ 44-45). The Attorney General presented no contrary evidence.

Second, even if AAM's members *could* exercise control over where their medicines ultimately are resold—presumably, through some elaborate series of contracts with wholesale distributors, retailers, pharmacies, hospitals, and all other entities in the lengthy drug supply chain—it is undisputed that AAM's members *do not* exercise that control. 4-App.-647-648 (R.Doc. 17 ¶¶4-5). Minnesota may not regulate their wholly out-of-state conduct based on the independent acts of third-parties, *see* pp. 38-42, *supra*, and that rule does not change even if some companies

could structure their businesses to avoid direct, extraterritorial regulation. Companies in other states are not required to pay for Minnesota to violate the Constitution.

The Seventh Circuit said exactly that in *Legato Vapors*. There, the court struck down an Indiana e-cigarette law that directly regulated "sales by an out-of-state manufacturer to an out-of-state distributor" or "out-of-state online retailer" if the distributor or online retailer then "re[sold] the e-liquids to Indiana retailers." 847 F.3d at 836. The Seventh Circuit held these were "impermissible extraterritorial regulation[s]" of sales that "occur[red] entirely outside the regulating state." *Id*. In reaching that conclusion, the court recognized that "to avoid regulation" out-of-state e-cigarette manufacturers "would need to include in [their] contracts with distributors and online retailers an effective, perhaps even foolproof, guarantee ensuring the e-liquid would not be resold to anyone in Indiana." *Id*. Notwithstanding that possibility, the court invalidated the law under the Commerce Clause.

None of the Attorney General's cases is to the contrary because none of them involved a direct regulation of wholly out-of-state commerce, like those at issue in *Styczinski*, *Frosh*, and *Edgar*. And certainly none upheld such a law because the regulated entity could conceivably avoid the regulation by adjusting its business operations. Instead, those cases involved laws that regulated only *in-state*

transactions and were alleged to have indirect extraterritorial effects.[24] In the context of that type of claim, it makes perfect sense to assess whether an out-of-state entity could avoid the effects of an in-state regulation by altering its business practice, because (pre-*Ross*) an in-state regulation's extraterritorial effects raised Commerce Clause concerns only if they "*necessarily require*[*d*] out-of-state commerce to be conducted according to in-state terms," *Cotto Waxo*, 46 F.3d at 794 (emphasis added)—*i.e.*, only if the law's extraterritorial effects are tantamount to direct regulation. *See Sorrell*, 272 F.3d at 110 (rejecting extraterritorial-effects challenge "because the statute does not *inescapably* require manufacturers" to follow state law) (citing *Cotto Waxo*, 46 F.3d at 794) (emphasis added). By contrast, when a law *directly* reaches outside the state's boundaries and controls wholly out-of-state conduct, no more is needed—the law "directly control[s] wholly out-of-state commerce" and therefore "'is invalid.'" *Styczinski*, 46 F.4th at 913 (citation omitted).

[24] *See SPGCC, LLC v. Blumenthal*, 505 F.3d 183, 187, 192-93,194 (2d Cir. 2007); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 107 & n.1, 110-11 (2d Cir. 2001); *Swanson v. Integrity Advance, LLC*, 870 N.W.2d 90, 92, 94-95 (Minn. 2015); *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 792 & n.1, 794 (8th Cir. 1995); *Hampton Feedlot, Inc. v. Nixon*, 249 F.3d 814, 817, 819 (8th Cir. 2001); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 646-48 (6th Cir. 2010); *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1101-04 (9th Cir. 2013); *TitleMax of Del., Inc. v. Weissmann*, 24 F.4th 230, 238-39 (3d Cir.), *cert. denied sub nom. TitleMax of Del., Inc. v. Vague*, 142 S. Ct. 2870 (2022).

E. The Act's anti-withdrawal provision exacerbates the Commerce Clause violation.

The Act's direct regulation of AAM's members' wholly out-of-state sales is alone sufficient to render the Act unconstitutional and affirm the preliminary injunction. But that conclusion is reinforced by the Act's imposition of a $500,000 penalty on manufacturers who withdraw their products from Minnesota to avoid the Act's price control. *See* Add. 15-16 (R.Doc. 42 at 15-16).

As the district court recognized, because AAM's members do not control where their products are resold by entities further down the supply chain, "the only sure way for a manufacturer to avoid liability [under the Act] is to either stop selling drugs altogether or to sell *all* of its drugs—including the vast majority that will never reach Minnesota—only at prices that comply with the Act." Add. 15-16 (R.Doc. 42 at 15-16). The anti-withdrawal provision puts a heavy thumb on the scale in favor of the latter option—pushing manufacturers to conform their prices to Minnesota's law *nationwide*, or else face a $500,000 penalty—and thus renders "[t]he extraterritorial reach of the Act … nearly unavoidable." Add. 15 (R.Doc. 42 at 15).

The Attorney General scarcely mentions the anti-withdrawal provision in his opening brief. That is not surprising, because that provision undermines his repeated refrain that Minnesota may regulate the out-of-state sales of AAM's members because those manufacturers have "voluntarily" subjected themselves to Minnesota regulation by choosing to be "licensed in Minnesota." Opening Br. 30; *see id*. at 22,

24, 26-28. To be clear, licensure in Minnesota "does not give the State *carte blanche* to regulate" manufacturers' out-of-state transactions. *Styczinski*, 46 F.4th 914; *see* pp. 34-38, *supra*. But even if it did, the anti-withdrawal provision proves that Minnesota gives manufacturers no such choice—certainly not those manufacturers, such as AAM's members, who obtained Minnesota licenses and whose products were sold into Minnesota by third parties *before* the Act became law.

It is no answer to say that those manufacturers may avoid Minnesota regulation by "return[ing] their licensure with the state." Opening Br. 27 & n.84. A manufacturer that relinquishes its license will be required to withdraw its products from Minnesota (Opening Br. 27), which falls squarely within the anti-withdrawal provision and would trigger the $500,000 penalty. This is a far cry from the portrait of a "voluntary" regulatory regime the Attorney General tries to paint.

* * *

The Commerce Clause imposes a clear rule: a state may regulate conduct that occurs within its borders, even if that regulation has effects in other states, but a state may not enact legislation that *directly* regulates conduct that occurs wholly outside its borders. The district court faithfully applied this Court's precedent in *Styczinski*, which the Attorney General concedes remains good law, to hold that the Act crosses that line. This Court should affirm.

II. The District Court did not abuse its discretion in granting the preliminary injunction.

The district court held that the Act is causing AAM's members irreparable harm, and that the remaining preliminary-injunction factors are "essentially a wash." Add. 17-20 (R.Doc. 42 at 17-20). The Attorney General does not challenge the district court's irreparable harm ruling, and none of the quibbles he raises on the remaining equitable factors has merit, much less establishes that the district court "abuse[d] [its] discretion" in granting the preliminary injunction. *Eggers v. Evnen*, 48 F.4th 561, 564 (8th Cir. 2022).

A. Applying settled precedent, the district court concluded that the public interest weighs in AAM's favor in part because "'it is always in the public interest to protect constitutional rights.'" Add. 19 (R.Doc. 42 at 19) (quoting *Carson*, 978 F.3d at 1061). The Attorney General argues that this principle is about "jealously guarding First Amendment rights," not the interests underlying the Commerce Clause. Opening Br. 34-35. This argument fails for two reasons.

To start, it is forfeited. The Attorney General dedicates exactly one sentence to this argument and does not cite any case to support it. *See Cox v. Mortg. Elec. Registration Sys., Inc.*, 685 F.3d 663, 674-75 (8th Cir. 2012) (parties forfeited argument by "failing to provide a meaningful explanation of the argument and citation to relevant authority in their opening brief").

In any event, the argument has no basis in law. *Carson* itself was not a First Amendment case but involved the Electors Clause in Article II of the Constitution, *see* 978 F.3d at 1059—a provision that does not grant individual rights, but confers authority on state legislatures, *see* U.S. Const. art. II, §1, cl. 2. Other cases have likewise applied the *Carson* principle outside the First Amendment context. *See, e.g.*, *D.M. ex rel. Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 998 (8th Cir. 2019) (Equal Protection Clause and Title IX); *Leaders of a Beautiful Struggle v. Balt. Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021) (holding in a Fourth Amendment case that "a state is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional") (citation omitted). There is no logical reason why the public interest is served by preventing states from violating the Electors Clause, but allowing violations of the Commerce Clause.

The Attorney General counters that "the public interest … is served by maintaining the ability to enforce [a] law adopted by the Minnesota legislature." Opening Br. 35 (quoting *Carson*, 978 F.3d at 1061). But that is not true of *unconstitutional* laws. *Carson* imposed an injunction against *executive* action that unconstitutionally overrode a Minnesota election law. 978 F.3d at 1059-63. It was the *valid* statute, not the unconstitutional executive action, whose enforcement was in the public interest. *Id*.

B. The balance of harms is also not in the Attorney General's favor. He argues that expanding access to prescription drugs produces "substantial" benefits that "outweigh[] … the choices of two manufacturers to allegedly abstain from price increases." Opening Br. 35. But even if the balance were so one-sided, that would not be a basis for reversal. The Attorney General identifies no case that has reversed a preliminary injunction enjoining a statute that is both likely unconstitutional and inflicts irreparable harm—"[t]he two most important considerations" of the preliminary-injunction calculus, *Bevis v. City of Naperville*, 85 F.4th 1175, 1188 (7th Cir. 2023)—simply because the law produces "substantial" economic benefits on third parties. The only case the Attorney General does cite—*Pharmaceutical Research & Manufacturers of America v. Concannon*, 249 F.3d 66 (1st Cir. 2001)—discussed the benefits of access to prescription drugs in the context of *upholding* the law against a Commerce Clause challenge under the *Pike* balancing analysis. *Id*. at 84. The court declined to address any of the other preliminary-injunction factors. *Id*. at 84-85.

But the balance is not so one-sided at all. Despite the Act's goal of reducing the rising costs of prescription drugs, it is likely to produce the exact opposite effect. The Act targets and imposes significant monetary liability *only* on generic and biosimilar manufacturers—those entities *most* responsible for reducing the cost of prescription drugs for patients (to the tune of *hundreds of billions* annually), and the

least responsible for rising drug prices—while exempting the brand manufacturers that even the Attorney General concedes are responsible for rising drug prices. *See* pp. 4-6, 11, *supra*. Generic and biosimilar companies already face enormous challenges bringing their drugs to market. *See* pp. 6-9, *supra*. Imposing massive monetary liability on top of that burden will only make it *more* difficult for these companies to produce the affordable medicines on which Minnesotans rely.[25]

That is all the more true given the "severe financial strain" that the generic industry is currently undergoing, Jewett, *Drug Shortages*, *supra*, with many generic and biosimilar manufacturers "struggling to stay in business," Ike Swetlitz, *Teva Plans to Cut Back Generic Drug Production Even As Shortages Intensify*, Bloomberg, May 18, 2023,[26] and some shutting down completely, *see* Jewett, *Drug Shortages*, *supra*. As a result of these hardships, "drug shortages in the United States" have "approach[ed] record levels," *id*., producing "devastating consequences for patients and health care providers," *Short Supply*, *supra*, at 5, as "[t]housands of patients are facing delays in getting treatments for cancer and other life-threatening diseases," Jewett, *Drug Shortages*, *supra*; *see also* p. 8, *supra*.

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[25] The Attorney General also references settlements involving generic manufacturers and antitrust- and securities-law claims. *See* Opening Br. 9 & n.39. Accusations of price-fixing or misstatements to investors, which are already illegal under the antitrust and securities laws, are no justification for the Act's targeting of *unilateral* pricing decisions by generic and biosimilar companies.

[26] https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages.

The Act's draconian penalties—and refusal to consider a manufacturer's increased costs—will only exacerbate this drug-shortage problem. By forbidding price increases necessary to keep products profitable and threatening generic and biosimilar manufacturers with severe penalties for making necessary price adjustments to maintain product viability, the Act will place increasing pressure on generic and biosimilar manufacturers to withdraw their products from the market entirely, and then impose a half-million dollar penalty for doing so. *See* 4-App.-653 (R.Doc. 17 ¶¶22-23); 4-App.-660-661 (R.Doc. 19 ¶¶22-23). Thus, the Act's price control will not only reduce the supply of affordable generic alternatives, but in doing so will increase demand for those drugs that competed with the discontinued generics—driving prices for those drugs even higher. This is not mere speculation: *both* of the examples of generic "price spikes" the Attorney General identified in his brief were for drugs in shortage. *See* Opening Br. 9 & n.41 (citing 1-App.-150 (R.Doc. 26-3 at 13)).[27] In the end, the Act will only make generics and biosimilars *less* available to patients in Minnesota, undermining the Act's goal of increasing access to affordable medications.

[27] The Attorney General's characterization (at 9-10) of these increases as being "unrelated to any increase in product cost" is not supported by the document he cites. In fact, the cited source recognizes that factors such as "limited potential to increase production" after a market exit by one manufacturer can "lead to increased prices." 1-App.-150 (R.Doc. 26-3 at 13).

CONCLUSION

The Court should affirm the judgment of the district court.

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Respectfully submitted,

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I hereby certify that:

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Dated: April 12, 2024

/s/ William M. Jay
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I certify that on April 12, 2024, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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